



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

216694

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

August 17, 2001

WARNING LETTER
CHI-42-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James A. Shupenus, RPh., Owner
Baker's Pharmacy
29 S. Main Street
Winchester, IL 62694

Dear Mr. Shupenus:

During an inspection of your oxygen repackaging facility conducted on June 25 & 26, 2001, Investigator Mark C. Peterson documented significant deviations from Current Good Manufacturing Practice (cGMPs) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. These deviations cause your firm's Oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding, are not in conformance with cGMP regulations. These deviations include, but are not limited to the following:

- Failure to adequately calibrate the [REDACTED] Oxygen analyzer that is used to assay the oxygen in accordance with manufacturer's instruction manual [21 CFR 211.160(b)(4)]. Investigator Peterson reported that your firm calibrates the [REDACTED] monthly, rather than each day or whenever cylinders of Oxygen are filled.
- Failure of batch production and control records to include complete information relating to the production and control of each batch [21 CFR 211.188]. For example, the inspection revealed that rather than record the actual gauge reading when a vacuum is pulled on the cylinders, the operator applies a check mark to the record instead of reporting the actual assay results. The production records reviewed by Investigator Peterson failed to contain the initials of the analyst who performs the vacuum gauge readings. The records also did not contain the initials/signature of the reviewer who reviewed the production record and authorized the release of the batch.
- Failure to establish written procedures that describe the handling of all written and oral complaints regarding Oxygen, USP, filled at your facility [21 CFR 211.198(a)].

Page 2

The above list of violations, as well as the Form FDA-483 Investigator Peterson issued and discussed with you, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm's Oxygen, USP, is in compliance with the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters so that they may take this information into consideration when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your response should be directed to the attention of George F. Bailey, Compliance Officer, at the above address.

Sincerely,

\s\

Raymond V. Mlecko
District Director